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| 10/765,430 | 01/26/2004 | Guillermo J. Tearney | 34834/US/2-475387-20 | 1546 |
| 7590 | | 11/08/2007 | EXAMINER | |
| GARY ABELEV | | | KHOLDEBARIN, IMAN K | |
| DORSEY & WHITNEY LLP | | | ART UNIT | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|-----------------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/765,430 | TEARNEY ET AL. |
| | Examiner I Kenneth Kholdebarin | Art Unit 3737 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-7, 9, 11-31, 33-36 and 40-43 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-7, 9, 11-31, 33-36 and 40-43 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date See Continuation Sheet.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: ref. no. 14 (interferometer) on page 9, paragraph [0036]; in the specification.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement-drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. Claims 1, 2, 4, 8, 36 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Z. Chen (Imaging thermally damaged tissue by polarization sensitive optical coherence tomography. OPTICS EXPRESS 212, Vol. 3, No.6 issued 14 September 1998).

Chen discloses an apparatus for identifying characteristics of tissue with a radiation source (SLD) configured to perform an axial scan of the tissue using radiation; and an imaging system (Fig. 1) with interferometer adapted to receive axial scan radiation based on the axial scan, and to process (detectors) data received from the reference arm and sample arm relating to the axial scan radiation to identify characteristics of the tissue, (See Figs. 1 and 4 where it shows the result of the processing the received data).

4. Claims 1-7, 9-11, 16-18, 21, 23, 27, 29, 30 31, 35, 36, 40, 41 are rejected under 35 U.S.C. 102(e) as being anticipated by Boppart (US 6,485,413).

Re claim 1: Boppart discloses an apparatus for identifying characteristics of tissue with a radiation source (10) configured to perform an axial scan of the tissue using radiation; and an imaging system (Fig. 1) with interferometer adapted to receive axial scan radiation

based on the axial scan, and to process (38) data received from the reference arm and sample arm relating to the axial scan radiation to identify characteristics of the tissue,

(See Figs. 1 and 2; col.1, lines 39-49; col.5 line 64- col.6. line 1).

Re claim 2-7, 21, 27 and 33: Boppart discloses an apparatus and method which has a computer with storage medium that contains radiation source to be the light source (10) or broad bandwidth (Col.6, line 12-15) or swept wavelength (to achieve very small instantaneous bandwidths at very high frequency 20-200kHz) and delivers to the tissue via an optical fiber (57) and the insertion device such as needle (372) to have distal end of the optical fiber adjacent to the tissue (See Fig. 2 and 25a).

Re claim 9, 11, 19 and 31: Boppart further discloses the imaging system and method that includes interferometer (19) for directing radiation into a reference arm (see fig. 2). Boppart further discloses that the imaging system could be combined with or without Doppler imaging ability (col.36, line 42-45).

Re Claim 16, 23, 29 and 35: Boppart further discloses the imaging system, method, (logical arrangement) and computer (42) having storage medium to identify the characteristic of the tissue by determining reflectance characteristic of the axial scan using interferometric ranging, and it is inherent to have a database as part of the system an apparatus in order to identify the characteristic of received data (See Abstract, line 5-8).

Re Claim 17 and 40: Boppart discloses the apparatus wherein the type of interferometric ranging is spectral domain (See col. 6 line 12-16).

Re claim 18 and 30: Chen discloses a method or logic arrangement of performing an axial scan of the tissue using radiation and processing data relating to the axial scan radiation based on the axial scan to identify characteristics of the tissue wherein a portion of the radiation emitted by radiation source is directed into a sample arm and received through the sample arm and the processing includes identifying characteristics of the tissue by processing the scan radiation including radiation received from the reference arm and comparing the characteristics of the tissue within an inherent database that contains normalized characteristic of the tissue, (See Fig. 1 and Fig. 4)

Re claim 18 and 30: Boppart discloses a method or logic arrangement of performing an axial scan of the tissue using radiation and processing data relating to the axial scan radiation based on the axial scan to identify characteristics of the tissue wherein a portion of the radiation emitted by radiation source is directed into a sample arm and received through the sample arm and the processing includes identifying characteristics of the tissue by processing the scan radiation including radiation received from the reference arm and comparing the characteristics of the tissue within an inherent database that contains normalized characteristic of the tissue, (Col. 5 line 25-30, col.5 64-col.6 line 1).

Re Claim 41: Boppart teaches an apparatus for identifying characteristics of tissue with a radiation source configured to perform the scanning of the tissue using radiation and an imaging system adapted to receive axial scan radiation based on the scan, and receive data relating to the scan is based on spectral domain (See col. 6 line 12-16, See Figs. 1 and 2; col.1, lines 39-49; col.5 line 64- col.6. line 1).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 5 and 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boppart in view of Tearney (US 6,111,645). The teachings of Boppart have been discussed above.

Re claim 12-15, 20: however, Boppart fails to disclose or fairly suggest the apparatus or a storage medium with a program stored to execute the process of the system wherein the processor performs one of the standard deviation or average deviation or slope of the axial reflectivity. Tearney '645 teaches the apparatus and method that comprising a signal-processing unit in electrical communication with detector and wherein the

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adjustable optical element is repetitively scanned and signal-processing unit compensates any non-uniform rate of change of phase delay.

Therefore in view of Tearney '645, it would have been obvious to one ordinary skill in the art at the time the invention was made to apply one of the above method by the processor unit of the apparatus claimed to process the received signal derived from the axial scan radiation in order to extract features of data to further predict the type of sample tissue.

7. Claims 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boppart (US6,485,413).

Re Claim 22, 28 and 34: Although Boppart '413 fails to specifically suggest use of statistical modeling, Boppart '413 teaches the study of the processing steps to identify the characteristic to the tissue based on the received signals. The received signal will be process on computer (42) that contains a storage medium.

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made that the statistical model used in applied statistics is to study and observe directly of the data received with the same unit over the time (longitudinal research). Observations of a variety of statistical attributes is a common way of studying relationships among the attributes of a single unit and this is clearly is the process that one ordinary skilled in the art would take to identify the characteristic of the tissue based on data received from the sample arm.

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8. Claims 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boppart (US6,485,413).

Re Claim 22: Although Boppart '413 fails to specifically suggest a storage medium storing a software program for identifying characteristics of the tissue wherein the software program, when executed by a processing arrangement is configured to cause the process arrangement to execute the steps, Boppart '413 teaches In situations where very high numerical aperture lenses are used the more exact expressions or algorithms must be programmed into the computer controller subsystem to maintain focus tracking on scanning process. Boppart further teaches processing data relating to the scan to identify the characteristics of the tissue received from sample arm. And it is inherent for any system that characterize the data to have a database to store or compare the data received from normalized characteristics of a plurality of that type of data (col. 17, line 22-26), Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made that a storage medium exist on a computer controller to store a program in order to execute the program for axial scan radiation that could include Doppler shift (col.36, line 42-45) or backscattering and further receiving and analyzing the information received.

9. Claims 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boppart in view of Tearney (US 6,111,645). The teachings of Boppart have been discussed above.

Re claim 42: however, Boppart fails to disclose or fairly suggest the apparatus or a storage medium with a program stored to execute the process of the system wherein the processor performs one of the standard deviation or average deviation or slope of the

axial reflectivity. Boppart discloses an apparatus for identifying characteristics of tissue with a radiation source (10) configured to perform an axial scan of the tissue using radiation; and an imaging system (Fig. 1) with interferometer adapted to receive axial scan radiation based on the axial scan, and to process (38) data received from the reference arm and sample arm relating to the axial scan radiation to identify characteristics of the tissue, (See Figs. 1 and 2; col.1, lines 39-49; col.5 line 64- col.6. line 1). Tearney '645 teaches the apparatus and method that comprising a signal-processing unit in electrical communication with detector and wherein the adjustable optical element is repetitively scanned and signal-processing unit compensates any non-uniform rate of change of phase delay.

Therefore in view of Tearney ' 645, it would have been obvious to one ordinary skill in the art at the time the invention was made to apply one of the above method by the processor unit of the apparatus claimed to process the received signal derived from the axial scan radiation in order to extract features of data to further predict the type of sample tissue.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Saidi discloses systems and methods for treating, diagnosing and predicting the occurrence of a medical condition; Tearney disclose System and method for identifying tissue using low-coherence interferometry; Jeon discloses Non-invasive body component concentration measuring apparatus and method of noninvasively

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measuring a concentration of a body component using the same; Miga discloses Apparatus and methods of brain shift compensation and applications of the same.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to I Kenneth Kholdebarin whose telephone number is 571-270-1347. The examiner can normally be reached on M-F 8 AM- 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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02/21/2007

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ELECTRONIC IMAGE
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Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date
04/22/2005, 07/25/2005, 08/22/2005, 10/31/2005, 11/07/2005, 11/14/2005, 01/23/2006, 02/21/2006, 03/17/2006, 06/22/2006,
08/28/2006, 12/08/2006.